



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Lippa, et al

Title: **(-)-1-(3,4-DICHLOROPHENYL)-3-AZABICYCLO[3.1.0]HEXANE, COMPOSITIONS THEREOF, AND USES AS A DOPAMINE-REUPTAKE INHIBITOR**

Application No.: 10/764,371

Filing Date: January 23, 2004

Examiner/Unit: Taofiq Solola/1626

Atty. Docket No.: 2370-006-06


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on this 12th day of September, 2005.


Susan M. Wanger

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97

TO THE COMMISSIONER FOR PATENTS:

In compliance with the duty of disclosure under 37 CFR § 1.56, Applicants submit herewith patents, publications, or other information for consideration during the examination of this application.

In accordance with 37 CFR § 1.97, the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made nor that the information cited in the statement is or is considered to be "material" to patentability as defined in 37 CFR § 1.56(b).

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees be deemed necessary, the Commissioner is hereby authorized to deduct any necessary fees from Deposit Account No. 07-1897.

For the sake of completeness, the undersigned would also like to bring the following pending unpublished provisional and nonprovisional US patent applications to the attention of the Office: (1) US Provisional Application 60/625,207 filed 11/5/04; (2) US Provisional Application 60/701,562 filed 7/22/05; (3) US Provisional Application 60/702,800 filed 7/26/05; (4) US Provisional Application 60/703,364 filed 7/27/05; (5) US Provisional Application 60/664,002 filed 3/21/05; (6) US Provisional Application 60/661,662 filed 3/8/05; (7) US Patent Application Serial No. 10/920,748 filed 8/18/04; and (8) US Patent Application Serial No. 11/205,956, filed 8/16/05. These pending applications are being brought to the attention of the Office since they are in a similar technical field as and share common ownership with the present application. These unpublished applications are being identified for the Office's attention only and are not intended or authorized to become part of the file wrapper of the present application. No representation is made that the foregoing unpublished applications are or are considered to be "material" to patentability as defined in 37 CFR § 1.56(b).

The present application was filed as a divisional of U. S. Application Serial No. 10/425,545, filed April 29, 2003 and relies on the earlier application for an earlier effective filing date under 35 USC 120. Consequently, as provided in 37 CFR § 1.98(d), only copies of the foreign patent documents and non-patent literature documents cited in the attached PTO SB-8a and 8b and not previously submitted with the information disclosure statement properly submitted in the earlier application are attached.

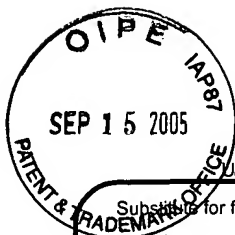
Date: September 12, 2005

Respectfully submitted,

GRAYBEAL JACKSON HALEY LLP

A handwritten signature in black ink, appearing to read "Jeffrey J. King", is written over a horizontal line.

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PTO/SB/08a (08-03)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 Of 4

Complete if Known

Application Number	10/764,371
Filing Date	January 23, 2004
First Named Inventor	Lippa, et al
Art Unit	1626
Examiner Name	Taofiq Solola
Attorney Docket Number	2370-006-06

U.S. PATENT DOCUMENTS

Exam. Initials	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	AA	US- 6,245,911	06/12/01	Imai, et al	Issued
	AB	US-6,204,284	03/20/01	Beer, et al	
	AC	US-6,194,000	02/27/01	Smith, et al	
	AD	US-6,121,261	09/19/00	Glatt, et al	
	AE	US-6,109,269	08/29/00	Rise, et al	
	AF	US- 5,985,864	11/16/99	Imai, et al	
	AG	US- 5,969,156	10/19/99	Briggs, et al	
	AH	US-5,911,992	06/15/99	Braswell, et al.	
	AI	US-5,762,925	06/09/98	Sagen	
	AJ	US- 5,574,052	11/12/96	Rose, et al	
	AK	US- 5,556,838	09/17/96	Mayer, et al	
	AL	US- 5,556,837	09/17/96	Nestler, et al	
	AM	US- 5,488,056	01/30/96	Bodick, et al	
	AN	US- 5,232,934	08/03/93	Downs	
	AO	US- 5,198,459	03/30/93	Imperato, et al	
	AP	US- 5,130,430	07/14/92	Shaw	
	AQ	US- 5,075,341	12/24/91	Mendelson, et al	
	AR	US- 5,039,680	08/13/91	Imperato, et al	
	AS	US- 4,591,598	05/27/86	Urbach, et al	
	AT	US- 4,521,431	06/04/85	Crookes	
	AU	US- 4,504,657	03/12/85	Bouzard, et al	
	AV	US- 4,435,419	05/06/84	Epstein, et al	
	AW	US- 4,336,268	06/22/82	Bruderer, et al	
	AX	US- 4,231,935	11/04/80	Fanshawe, et al	
	AY	US- 4,196,120	04/01/80	Fanshawe, et al	
	AZ	US- 4,131,611	12/26/78	Fanshawe, et al	
	BA	US- 4,118,417	10/03/78	Epstein	
	BB	US- 4,118,393	10/03/78	Fanshawe, et al	
	BC	US- 4,088,652	05/09/78	Fanshawe, et al	
	BD	US- 4,022,652	05/10/77	Hirano, et al	
	BE	US-3,892,722	07/01/75	Hoffman, et al	
	BF	US-6,372,919	04/16/02	Lippa, et al	
	BG	US-6,569,887	05/27/03	Lippa, et al	
	BH	US-6,716,868	04/06/04	Lippa, et al	
	BI	USSN 10/764,373 2004-0157870	08/12/04	Lippa, et al	
	BJ	USSN 10/764,375 2004-0157908	08/12/04	Lippa, et al	
	BK	USSN 10/702,397 2004-0102638	05/27/04	Russell, et al	
	BL	USSN 10/621,435 2004-0127541	07/01/04	Codd, et al	
	BM	USSN 10/466,457 2004-0132797	07/08/04	Lippa, et al.	

FOREIGN PATENT DOCUMENTS						
Exam. Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
	BN	BE 858,683	12/30/82	BE (In French w/English Abstract)		Published
	BO	BE 893,707	12/30/82	BE (In French w/English Abstract)		Published
Examiner Signature				Date Considered		

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STATEMENT BY APPLICANT**

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Sheet

3

Of

4

Complete if Known

Application Number

Filing Date

January 23, 2004

First Named Inventor

Lippa

Art Unit

1626

Examiner Name

Taofiq Solola

Attorney Docket Number

2370-006

NON PATENT LITERATURE DOCUMENTS

Exam. Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BP	BALDESSARINI, R. <u>Drugs and The Treatment of Psychiatric Disorders</u> . Goodman & Gilman's The Pharmacological Basis of Therapeutics 9 th Edition. Hardman et al. eds. 1996. p. 399 and Ch 18:431-459, McGraw-Hill, New York	
	BQ	BLUM, et al., <u>Dopamine D2 Receptor Gene Variants: Association and Linkage Studies In Impulsive-Addictive-Compulsive Behavior</u> . Pharmacogenetics 5:121-141, 1996.	
	BR	BRAY, G. <u>A Concise Review On The Therapeutics of Obesity</u> . Nutrition 16:953-960, 2000.	
	BS	CROWN, W. <u>Economic Outcomes Associated With Tricyclic Antidepressant And Selective Serotonin Reuptake Inhibitor Treatments For Depression</u> . Acta Psychiatr. Supp. 2000; 403:62-6.	
	BT	D'AQUILA, et al, <u>The Role Of Dopamine In The Mechanism of Action of Antidepressant Drugs</u> . Eur. J. Pharmacol. 405:365-373, 2000.	
	BU	EPSTEIN, et al., <u>1-ARYL-3-AZABICYCLO[3.1.0]HEXANES, A New Series of Non-Narcotic Analgesic Agents</u> . J. Med. Chem. 24(5):481-90, 1981.	
	BV	EPSTEIN, et al., <u>Bicifadine: Non-Narcotic Analgesic Activity of 1-ARYL-3-AZABICYCLO[3.1.0]HEXANES</u> . NIDA Res. Monogr. 41:93-98, 1982.	
	BW	FRAZER, A. <u>Norepinephrine Involvement In Antidepressant Action</u> . J. Clin. Psychiatry. 61(10):25-30, 2000.	
	BX	FREDMAN, et al., <u>Partial Response, Nonresponse, and Relapse With Selective Serotonin Reuptake Inhibitors In Major Depression: A Survey of Current "Next-Step" Practices</u> . J. Clin. Psychiatry 61(6):403-8, 2000.	
	BY	Hackh's Chemical Dictionary, 4 th Edition, 1969, Julius Grant, ed., McGraw-Hill Book Company, New York, pp. 474-75	
	BZ	Harrison's Principles of Internal Medicine 2485-2503 (Fauci, et al., eds., 14 th ed. 1998)	
	CA	HITRI, et al., <u>Molecular, Functional and Biochemical Characteristics of The Dopamine Transporter: Regional Differences and Clinical Relevance</u> . J. Clin. Pharmacol. 17:1-22, 1994.	
	CB	HOFFMAN, et al., <u>Localization and Dynamic Regulation of Biogenic Amine Transporters In The Mammalian Central Nervous System</u> . Front. In Neuroendocrinol. 19(3): 187-213, 1998.	

NON-PATENT LITERATURE DOCUMENTS			
Exam. Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CC	KIYATKIN, E. <u>Dopamine Mechanisms of Cocaine Addition</u> . Int. J. Neurosci. 78:75-101, 1994.	
	CD	KREEK, M. <u>Cocaine, Dopamine and The Endogenous Opioid System</u> . J. Addict. Dis. 15:73-96, 1996.	
	CE	LEONHARDT, et al., <u>New Approaches In The Pharmacological Treatment of Obesity</u> . Eur. J. Nutr. 38:1-13, 1999.	
	CF	MEYERSON, et al., <u>Allosteric Interaction Between The Site Labeled by [3H]Imipramine and The Serotonin Transporter In Human Platelets</u> . J. Neurochem. 48(2):560-65, 1987.	
	CG	NAGATSU, et al., <u>Changes In Cytokines And Neorotrophins In Parkinson's Disease</u> . J. Neural. Transm. Suppl. 60:277-290, 2000.	
	CH	NOBLE, E. <u>Polymorphisms of The D2 Dopamine Receptor Gene and Alcoholism and Other Substance Use Disorders</u> . Alcohol. Supp. 2:35-43, 1994.	
	CI	PORTER, et al., <u>Single Dose Comparison of Bicifadine, Codeine, and Placebo in Postoperative Pain</u> . Current Therapeutic Research. 30(3):156-160, August 1981.	
	CJ	SCATES, et al., <u>Reboxetine: A Selective Norepinephrine Reuptake Inhibitor For The Treatment Of Depression</u> . Ann. Pharmacother. 34(11):1302-12, 2000.	
	CK	SIMON, et al., <u>TCAs or SSRIs As Initial Therapy For Depression?</u> J. of Family Practice. 48:845-46, 1999.	
	CL	STACY, et al., <u>Treatment Options for Early Parkinson's Disease</u> . Am. Fam. Phys. 53:1281-87, 1996.	
	CM	SULLIVAN, et al., <u>Mechanisms of Appetite Modulation By Drugs</u> , Federation Proceedings, Vol. 44, No. 1, Part 1, pp. 139-144, 1985.	
	CN	WANG, et al., <u>The Oral Analgesic Efficacy of Bicifadine Hydrochloride In Postoperative Pain</u> . J. Clin. Pharmacol. 22(4):160-164, April 1982.	
	CO	WONG, et al., <u>Reboxetine: A Pharmacologically Potent, Selective, and Specific Norepinephrine Reuptake Inhibitor</u> . Biol. Psychiatry. 47(9):818-29, 2000.	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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